

contained. The headache tablets contained acetanilid and would be dangerous to health when used as directed, and the label failed to reveal the consequences which might result from their use.

On June 17, 1940, the United States attorney for the Southern District of Illinois filed a libel against 1,005 bottles of Aspirol Tablets and 1,416 bottles of headache tablets at Bloomington, Ill., alleging that the articles had been shipped in interstate commerce on or about July 3, 1939, and April 19, 1940, by the J. R. Watkins Co. from Winona, Minn.; and charging that they were misbranded.

The Aspirol Tablets were alleged to be misbranded in that the name was false and misleading because it was derived from the ingredient aspirin; whereas they contained other active ingredients, including acetophenetidin and caffeine citrate. They were alleged to be misbranded further in that they were fabricated from two or more ingredients and the label failed to bear a statement of the quantity of acetophenetidin contained in each tablet.

The Headache Tablets were alleged to be misbranded in that the statements in the labeling, "Headache * * * If pain is severe take two tablets for first dose * * * Directions: Adults: One tablet every 2 hours until relieved. Take no more than 4 tablets in 24 hours. Children: Over 10 (only) half dose," were false and misleading since they created the impression that the article constituted an appropriate treatment for headache; whereas it was not such a safe and appropriate remedy but was a dangerous drug, and the label failed to reveal the fact, material in the light of the representations made as quoted hereinbefore, that the use of the article in accordance with the directions might cause serious blood disturbances, anemia, collapse, or a dependence on the drug. It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling.

On February 25, 1941, G. C. Heberling Bros., Bloomington, Ill., having appeared as claimant and having consented to the entry of a decree, judgment of condemnation was entered and it was ordered that the Aspirol Tablets be released under bond conditioned that they be properly relabeled under the supervision of the Food and Drug Administration and that the headache tablets be destroyed.

329. Misbranding of Watkins Laxative Cold Tablets. U. S. v. 300 Boxes of Laxative Cold Tablets. Default decree of condemnation and destruction. (F. D. C. No. 2310. Sample No. 323-E.)

This product would be dangerous to health when used as directed in the labeling and was not labeled to indicate the consequences that might result from its use. It was misbranded further because it was labeled to indicate that it was a safe and appropriate remedy for the conditions for which it was recommended and in the other respects referred to hereinafter.

On July 6, 1940, the United States attorney for the Western District of North Carolina filed a libel against 300 boxes of laxative cold tablets at Charlotte, N. C., alleging that the article had been shipped in interstate commerce on or about February 15, 1940, by the J. R. Watkins Co., from Newark, N. J.; and charging that it was misbranded.

Analysis showed that the article contained 1.9 grains of acetanilid (1.9 grains per tablet), total alkaloids including quinine and alkaloids of belladonna (0.25 grain per tablet), and extracts of plant drugs including a laxative drug.

The article was alleged to be misbranded in that the following statements (tin container) "Directions * * * For Cold Symptoms. Adult Dose: Take two tablets every three hours until three doses have been taken. This should cause the bowels to move freely. Then take one tablet three times a day until all symptoms are removed. For Casual Headaches. Adult Dose: Two tablets to be followed by one every three hours when necessary (not exceeding 6 in 24 hours). If headaches persist or return frequently, consult your physician. For children. Over ten years of age one-half adult dose; over five years of age one-fourth adult dose," and (circular) "At The First * * * Chill, Or Fever * * * Take Watkins Laxative Cold Tablets * * * Watkins Laxative Cold Tablets contain ingredients that are selected to be used to treat the symptoms of colds and headaches. Especially good for sneezing or nasal discharge, headache and other disagreeable symptoms usually associated with colds. They increase the action of the bowels. In this manner they help to carry off from the system waste substances that tend to keep up the headache

and other discomforts and aid in warding off the effects or in lessening the severity of symptoms. When you find yourself sneezing, chilly and have other symptoms of a cold coming on, do not wait but take early precautions to check their advance and to throw them off before they become severe. The convenience of Watkins Laxative Cold Tablets is something to be appreciated. They are a compound of medicines that have laxative and other properties which assist in overcoming the disagreeable symptoms which are associated with colds. Take as directed and rest as much as possible," and similar directions in various foreign languages, were false and misleading since they created the impression that it constituted an appropriate treatment in these conditions; whereas it was not such a safe and appropriate remedy but was a dangerous drug; and also because the label failed to reveal the fact, material in the light of the representations made as quoted above, that its use in accordance with the directions might cause serious blood disturbances, anemia, collapse, or a dependence on the drug.

It was alleged to be misbranded further in that the statement "Total alkaloids 1/25,000 grain per tablet" and similar statements in foreign languages were false and misleading since the article was found to contain total alkaloids extremely in excess of this amount.

The article was alleged to be misbranded further in that the labeling did not bear adequate directions for use; in that the labeling did not bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods of administration or application, in such manner and form, as were necessary for the protection of users; and in that it was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof as quoted above.

On July 29, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

330. Adulteration and misbranding of One Minute Toothache Stick. U. S. v. 20 Dozen Packages of Toothache Stick. Default decree of destruction. (F. D. C. No. 2159. Sample No. 5305-E.)

This product contained carbolic acid. It would be dangerous to health when used as directed in the labeling and would not be efficacious for certain conditions for which it was recommended in the labeling. It also contained a smaller percentage of carbolic acid than that declared on the label.

On or about June 7, 1940, the United States attorney for the Western District of Kentucky filed a libel against 20 dozen packages of toothache stick at Louisville, Ky., alleging that the article had been shipped in interstate commerce on or about April 12, 1940, by the One Minute Remedies Co. from St. Louis, Mo.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of carbolic acid (23 percent), paraffin, cotton, and small amounts of oils of clove and cinnamon.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, 30 percent carbolic acid. It was alleged to be misbranded in that the following statements contained in the accompanying circular were false and misleading, since they purported and represented that it would be efficacious in the conditions named therein: "More than thirty-eight years ago this company determined that the crude and old-fashioned remedy of toothache drops must be abandoned for something better. Drops scald the mouth and gums and lead to sores which may produce serious conditions. After many experiments this Toothache Stick was considered the best; and millions of satisfied users in the last thirty-eight years testify that it stops toothache instantly." It was alleged to be misbranded further in that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling: "Directions: Remove all substances from the tooth, cut a piece of the stick the size required and press firmly into the tooth. Where no cavity exists, press flat and apply as a plaster." It was alleged to be misbranded further in that it was fabricated from two or more ingredients and the label on the bottle did not bear the common or usual name of the active ingredients.

The article was also alleged to be misbranded in violation of the Federal Caustic Poison Act, as reported in notices of judgment published under that act.

On October 15, 1940, no claimant having appeared, judgment was entered ordering that the product be destroyed.